

- (i) Physiological well being.
- (ii) Functional status.
- (iii) Cognitive ability.
- (iv) Social/behavioral functioning.
- (v) Quality of life of participants.
- (4) Effectiveness and safety of staff provided and contracted services, including the following:
 - (i) Competency of clinical staff.
 - (ii) Promptness of service delivery.
 - (iii) Achievement of treatment goals and measurable outcomes.
- (5) Nonclinical areas, such as grievances and appeals, transportation services, meals, life safety, and environmental issues.
- (b) *Basis for outcome measures.* Outcome measures must be based on current clinical practice guidelines and professional practice standards applicable to the care of PACE participants.
- (c) *Minimum levels of performance.* The PACE organization must meet or exceed minimum levels of performance, established by CMS and the State administering agency, on standardized quality measures, such as influenza immunization rates, which are specified in the PACE program agreement.
- (d) *Accuracy of data.* The PACE organization must ensure that all data used for outcome monitoring are accurate and complete.

§ 460.136 Internal quality assessment and performance improvement activities.

- (a) *Quality assessment and performance improvement requirements.* A PACE organization must do the following:
 - (1) Use a set of outcome measures to identify areas of good or problematic performance.
 - (2) Take actions targeted at maintaining or improving care based on outcome measures.
 - (3) Incorporate actions resulting in performance improvement into standards of practice for the delivery of care and periodically track performance to ensure that any performance improvements are sustained over time.
 - (4) Set priorities for performance improvement, considering prevalence and severity of identified problems, and give priority to improvement activities that affect clinical outcomes.
 - (5) Immediately correct any identified problem that directly or poten-

tially threatens the health and safety of a PACE participant.

(b) *Quality assessment and performance improvement coordinator.* A PACE organization must designate an individual to coordinate and oversee implementation of quality assessment and performance improvement activities.

(c) *Involvement in quality assessment and performance improvement activities.* (1) A PACE organization must ensure that all interdisciplinary team members, PACE staff, and contract providers are involved in the development and implementation of quality assessment and performance improvement activities and are aware of the results of these activities.

(2) The quality improvement coordinator must encourage a PACE participant and his or her caregivers to be involved in quality assessment and performance improvement activities, including providing information about their satisfaction with services.

§ 460.138 Committees with community input.

A PACE organization must establish one or more committees, with community input, to do the following:

- (a) Evaluate data collected pertaining to quality outcome measures.
- (b) Address the implementation of, and results from, the quality assessment and performance improvement plan.
- (c) Provide input related to ethical decisionmaking, including end-of-life issues and implementation of the Patient Self-Determination Act.

§ 460.140 Additional quality assessment activities.

A PACE organization must meet external quality assessment and reporting requirements, as specified by CMS or the State administering agency, in accordance with § 460.202.

Subpart I—Participant Enrollment and Disenrollment

§ 460.150 Eligibility to enroll in a PACE program.

- (a) *General rule.* To enroll in a PACE program, an individual must meet eligibility requirements specified in this section. To continue to be eligible for